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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1141 Central Parkway
Cincinnati, OH 45202

February 25, 1997

WARNING LETTER
CIN-WL-97-223

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Gary Mintz, Vice President
Racom Products, Inc.
5504 State Road
Cleveland, OH 44134-2299

Dear Mr. Mintz:

During an inspection of your firm located in Cleveland, OH, on 1/27-30/97, our Investigator determined that your firm manufacturers ECG telemetry systems and battery pack accessories for cardiac monitors. ECG telemetry systems and monitor battery packs are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish and document a formal quality assurance program. There is no assigned QC person to review test records or approve release of finished devices.

2. Failure to conduct planned and periodic audits of the quality assurance program in accordance with written procedures. For example, no audits of the quality assurance program have been performed for at least 3 years and no procedures are in place to conduct such audits.

3. Failure to establish complete Device Master Records (DMR). For example: the DMR is not signed and dated to document approval and effective date; there are no assembly instructions for the LBE, TSS and TRS devices; original schematics for these devices are not signed and there

is no formal approval of changes in these documents; and there are no packaging and labeling specifications.

4. Failure to establish formal written Finished Device Testing procedures. For example: these documents lack an implementation date and approval signature; changes to these procedures are not approved by a designated individual; and test specifications are not always included in the test procedures, such as TRS output voltages and TSS frequency values.

5. Failure to establish complete Final Test records. For example, the 14 out of 54 CTS final test records reviewed were not reviewed and approved by a second individual.

6. There is no formal, approved written procedure for setup and calibration of the TRS.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pending applications for premarket approval (PMA's) or export approval requests will be approved and no premarket notifications (Section 510(k)'s) will be found to be substantially equivalent for products manufactured at the facility in which that above GMP violations were found until the violations have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to the U.S. Food and Drug Administration, 1141 Central Parkway, Cincinnati, OH 45202-1097, Attention Charles S. Price, Compliance Officer. If you have any questions, you may call Mr. Price at (513) 684-3501, extension 165.

Sincerely yours,

John R. Marzilli
District Director
Cincinnati District